

MAR 30 2005

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Special 510(k) Summary For miniMaster Ultrasonic Scaler

1. SPONSOR

E.M.S. Electro Medical Systems SA
Ch. de la Vuarpillière 31
CH - 1260 Nyon
Switzerland

Contact Person: Suzanne Fassio-Hardy
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Date Prepared March 17, 2005

2. DEVICE NAME

Proprietary Name: miniMaster
Common/Usual Name: Ultrasonic Scaler
Classification Name: Ultrasonic Scaler

3. PREDICATE DEVICES

EMS Kermit (K992504)

4. INTENDED USE

- Removing supra and subgingival calculus deposits and stains from the teeth
- Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planing
- Releasing crowns, bridges, inlays and posts as well as condensing gutta percha
- Plugging for amalgam condensation
- Amalgam burnishing
- Preparing, cleaning, and irrigating root canals

- Preparing approximal cavities
- Cementing inlays and onlays
- Retrograde preparation of root canals

5. DEVICE DESCRIPTION

The miniMaster is an ultrasonic scaler consisting of a main chassis containing an external electric power supply, controls and displays, ultrasonic generator, and a bottle-fed irrigation system. A 2-step footswitch is connected to the main chassis by a footswitch cord. A handpiece is connected to the main chassis by a handpiece cord, with irrigant flow control located on the cord itself. Instruments designed for specific dental procedures are attached to the distal end of the handpiece.

Two versions of the miniMaster will be commercially distributed in the US, one with and the other without the capability for dry work.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The modifications made to the parent EMS Kermit to produce the proposed miniMaster were implemented to improve the functional performance and ease of use of the ultrasonic scaler. These modifications do not alter the intended use or fundamental scientific technology of the device.

The intended uses of the proposed miniMaster and predicate EMS Kermit are identical. Both the proposed and parent devices are ultrasonic scalers intended for use in dental and periodontal cleaning, preparatory, and restorative procedures. All of the procedures for which the miniMaster is indicated were cleared for use with the EMS Kermit.

The modifications made to the parent EMS Kermit to produce the proposed miniMaster include the following:

- Conversion of internal to external electrical power supply
- Cosmetic changes to the C-51 ultrasonic generator

- Change from external water supply to bottle irrigation with a peristaltic pump
- Compatibility with Universal Piezon Handpiece
- Addition of newly designed instruments
- Movement of irrigant flow control to handpiece cord
- Minor design changes including reorientation of pump in housing and addition of a handpiece cord disconnect on the housing

The appropriate design verification and design validation activities were conducted to address the potential risks associated with the modified device that were identified in the Risk Analysis. The results confirm that the modified miniMaster is safe and effective for the dental and periodontal cleaning, preparatory, and restorative procedures listed in Section 8.

The similarities in intended use, technical specifications, and functional performance between the miniMaster and the parent EMS Kermit lead to a conclusion of substantial equivalence between the proposed and parent devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 30 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

E.M.S. Electro Medical Systems SA
C/O Cynthia J. M. Nolte, PhD., RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K050710
Trade/Device Name: MiniMaster Ultrasonic Scaler
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: March 17, 2005
Received: March 21, 2005

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu S. Lin', with a stylized flourish at the end.

Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K05 07 10

Device Name: miniMaster Ultrasonic Scaler

Indications for Use:

The miniMaster is an ultrasonic scaler that is intended for the following:

- Removing supra and subgingival calculus deposits and stains from the teeth
- Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planing
- Releasing crowns, bridges, inlays and posts as well as condensing gutta percha
- Plugging for amalgam condensation
- Amalgam burnishing
- Preparing, cleaning, and irrigating root canals
- Preparing approximal cavities
- Cementing inlays and onlays
- Retrograde preparation of root canals

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Murphy for ODE
Division Sign-Off
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K050710